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Eckart Matthes

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27387

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12/15/2008

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EXAMINER

EPPS FORD, JANET L

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## DETAILED ACTION

### ***Response to Arguments***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. 1, 2, 5-7, 9-11 and 16-22 are presently pending in the instant application.

### ***Claim Rejections - 35 USC § 103***

3. Claims 1-2, 5, 7, 9-11, 17-20, and 22 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Uhlmann et al. and Nielsen et al. in view of Norton et al. (1996) and Mata et al., for the reasons of record.
4. Applicant's arguments filed 11-20-2008 have been fully considered but they are not persuasive. First, Applicants summarized the claimed invention in an effort to distinguish it from the prior art. Applicants described the claimed invention as covering an oligonucleotide which is capable of binding to a telomerase protein simultaneously on two sites. Applicants argued that the oligonucleotides can bind both the template region of the telomerase RNA and at the same time it is able of binding to the telomerase protein. Applicants further argued that *"[T]his dual binding is a very important feature of the invention. The dual binding is the reason why the oligonucleotide according to the invention is enormously effective, more than other inhibitors of telomerase in the state of the art."*
5. In regards to the cited prior art, again Applicants reiterated their position regarding the differences in the "n" and "p" portions of the claimed oligonucleotides in

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contrast to the number of modified subunits in prior art compounds, specifically in regards to the Norton et al. reference.

In response to the examiner's statement that "[A]bsent evidence of unexpected results, it would have been obvious to the ordinary skilled artisan to combine the teachings of the above-cited references in the design of the present invention," Applicants suggested that the examiner review the previously submitted Declaration of Dr. Eckhart Matthes. According to Applicants, the "functionality of applicant's molecules is fully explicated in the Mattes Declaration. However contrary to Applicant's assertions, the Matthes Declaration did not provided any experimental comparative data that would clearly suggest that the combination of the cited references would not have produced oligonucleotides having the same properties as the claimed oligonucleotides. The Declaration was essentially the opinions of Dr. Matthes in response to the rejection of record. Dr. Matthes summarized his response to the rejection of the instant claims under 35 USC § 103 by stating:

"None of the references teach the formulas used in present invention, wherein n is at least 10 and not more than 20, and p is at least 3 and not more than 17 wherein the oligonucleotide structure comprises a terminal amino group. Further, in none of the documents is the use of the chimeric ODNs, as described in present invention, taught or suggested."

The above statement does not represent evidence that would render the claimed invention non-obvious, as stated in the prior Office Action, absent evidence of any unexpected results, one of ordinary skill in the art would have been motivated to make

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the oligomers of the present invention to comprise wherein  $n$  is at least 10 and not more than 20, and  $p$  is at least 3 and not more than 17, since the Uhlmann et al. clearly teach that chimeric PNA/DNA oligonucleotides of any sequence can be readily prepared, and Norton et al. discloses the nucleotide structure of an oligomer (15 base pairs in length; i.e. satisfying  $n$  and  $p$ ) that recognizes the RNA component of human telomerase and inhibits the activity of the enzyme. Additionally, Norton et al. further observed that phosphorothioate (PS) oligomers inhibit telomerase in a non-sequence selective fashion. Furthermore, it was also known in the art prior to the filing of the instant invention that hexameric phosphorothioate oligomers of any sequence function to inhibit telomerase activity and arrests growth of Burkitts lymphoma cells, see Mata et al. Although, Applicants argued that the oligonucleotides of the present invention are unique to the extent that they can bind both the template region of the telomerase RNA and at the same time it is able of binding to the telomerase protein, Norton et al. clearly teach that phosphorothioate oligonucleotides bind the RNA component of telomerase, and further inhibits the function of the telomerase enzyme. Absent evidence to the contrary, compounds produced by the combination of the cited references would have the same dual binding properties as the claimed oligonucleotides.

Regarding the rationale for combining prior art elements according to known methods to yield predictable results, all of the claimed elements were known in the prior art and one skilled in the art could have combined the element as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

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The differences in regards to the number of “n” and “p” nucleotides in the claimed oligonucleotides constitutes merely a difference in design choice, since the general teachings of chimeric PNA/DNA, and the role of phosphorothioate modified oligonucleotides and PNA in telomerase binding and inhibition are known in the art.

***Conclusion***

6. Claim 6 remains objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Ford/

Primary Examiner, Art Unit 1633

*JLE*